more isolated polypeptides. Group V includes claims 19 and 20 drawn to an antibody and a composition comprising the antibody. The restriction requirement is respectfully traversed.

In order to be responsive, applicant hereby elects Group IV, including claims 13-18 and 28-30. The claims which the examiner considers to be in Groups I-III and VI-VIII have now been deleted without prejudice toward the continuation of prosecution thereof in continuing applications. The restriction requirement is respectfully traversed insofar as Groups IV and V are concerned. It should be noted that claim 1 has now been rewritten as claim 13 in independent form.

The examiner states that Groups IV and V are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions or different effects. As a result, the examiner states that different and distinct searches will have to be performed. This part of the restriction requirement is respectfully traversed.

The restriction requirement is respectfully traversed insofar as the antibody of claim 19 is considered to be an independent and distinct invention from the polypeptide of claim 13. Claim 19 reads:

> 19. An antibody elicited by a polypeptide of claim 13 or a functional portion thereof.

Applicants hereby concede that, if the polypeptide of claim 13 were available to the prior art (which includes knowledge of its biological activity as set forth in the specification), it would be *prima facie* obvious, within the meaning of 35 U.S.C. §103, for one of ordinary skill in the art to make an antibody which is specific to such protein. Techniques of raising antibodies, including monoclonal antibodies, are well known and the Patent and Trademark Office routinely rejects claims to monoclonal antibodies as being obvious if the protein against which it is specific is known to the prior art.

It should clearly be understood that the present admission is a one-way admission only. Applicants do not concede that if an antibody is known which happens to bind to a polypeptide of claim 13, this would necessarily make the polypeptide of claim 13 obvious or unpatentable. Furthermore, applicants do not concede that all monoclonal antibodies specific for a polypeptide of claim 13 are necessarily obvious. Specific monoclonal antibodies may exist having unexpected properties which would not be obvious from prior art knowledge of the protein to which it is specific. However, in the present case, claim 19 is a broad claim to any antibody elicited by a polypeptide of claim 13 and the present concession is simply that there are antibodies within the scope of claim 19 which would not be patentable and would be *prima facie* obvious in the sense of 35 U.S.C. §103 if the protein of claim 13, including its biological properties, were

known to the prior art. Knowing the biological activity of such protein, one of ordinary skill in the art would have been motivated to make an antibody for the purpose of immunoaffinity purification or for the purpose of blocking its activity. The techniques for doing so are well known.

In light of the present admission and the provisional election of the protein claims of Group IV, a restriction requirement cannot be maintained. If the elected protein claims proceed to issue, any patent issuing on the antibody would have to be subject to an obviousness-type double patenting rejection in view of the above admission. See MPEP §804.II.B.1. relating to double-patenting rejections, which states:

> In determining whether a non-statutory basis exists for a double-patenting rejection, the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent? If the answer is yes, then "obvious-type" non-statutory double-patenting rejection may be appropriate.

However, such a double patenting rejection cannot be made in light of 35 U.S.C. §121. Reference is made to Section 803.01 of the MPEP, where it states:

> Notwithstanding the fact that this section of the statute [35 U.S.C. 121] apparently protects the applicants against the dangers that previously might have resulted from compliance with an improper requirement for

> restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. [Emphasis original]

See also 37 C.F.R. §1.601(n) defining the concept of patentably distinct inventions from the interference perspective. This rule states:

> Invention "A" is the **same patentable invention** as an invention "B" when invention "A" is the same as (35 USC 102) or is obvious (35 USC 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Here, assuming the protein of claim 13 (invention "B") is prior art to the antibody of claim 19 (invention "A"), the antibody is *prima facie* obvious in light of applicants' admission. Thus, both claims are drawn to the same patentable invention. If they are drawn to the same patentable invention for interference purposes, they should be considered the same patentable invention for all purposes, despite any distinction in the material *per se*. As indicated above, no restriction requirement can be made which would result in the issuance of two patents for the same invention.

MPEP §803 refers to the case of *In re Lee*, 199 USPQ 108 (Comm'r for Pat 1978) as holding that restriction should not be required if there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. §103. However, such a two-way admission

is not necessary as even the one-way admission presently being made is sufficient to result in two patents directed to the same invention. If an antibody claim in one patent would be obvious from a protein claim in another patent, then the two claims are not patentably distinct and the imprimatur of MPEP §803.01 quoted hereinabove must be invoked.

It should be noted that this identical issue has already been made the subject of a petition to the Commissioner by the undersigned with respect to another case and Deputy Director Mary C. Lee, in a decision published as *In re Gold*, 42 USPQ2d 1095 (Comm'r Pats 1996) confirmed that, in such a circumstance, restriction requirement is not applicable. Note particularly where it states at 1096:

> At this point it is noted that the fact that there is an admission that the antibody is obvious in view of the peptide but not an admission that the peptide is obvious over the antibody would not change this decision because the Office policy that "no restriction requirements be made which might result in the issuance of two patents for the same invention" would still control.

As all of the claims to the non-elected Groups other than Groups IV and V have been deleted and as Group V must be examined with Group I for the reasons discussed above, all of claims 1, 14-20, 28-30 and 32 presently appearing in this case should be examined in the present application.

The examiner states that each group detailed above reads on patentably distinct SEQ ID NOs., and that each

sequence is patentably distinct because the sequences are structurally unrelated sequences and a further restriction is applied to each group. The examiner states that each sequence is patentably distinct because the sequences are structurally unrelated. The examiner states that applicant must further elect a single SEQ ID NO. and that examination will be restricted only to the selected SEQ ID NO. and this should not be construed as a species selection. This part of the restriction requirement is also respectfully traversed.

In order to be responsive, applicant hereby elects the polypeptide sequence of SEQ ID NO:24, which appears in Figure 54. It is urged, however, that SEQ ID NOs:11, 14, 16 and 24, as well as the polypeptide expressed by the expression plasmid of claim 31, are all minor variants of the same human OCP protein. The examiner is incorrect in stating that each of these sequences are physically and functionally distinct chemical entities. They have the same function and are substantially the same sequence. Therefore at least SEQ ID NOs:11, 14, 16 and 24, and the product of claim 32, should be considered to be directed to the same invention (i.e., human OCP). Reconsideration and withdrawal of this part of the restriction requirement is therefore also respectfully urged.

The examiner states that Group IV contains claims directed to the following patentably distinct species of the claimed invention:

(1) A polypeptide having a molecular weight of 10 kD to 100 kD (claim 16),

(2) A polypeptide having a molecular weight of about 25 kD (claim 17), and

(3) A polypeptide having a molecular weight of about 70-80 kD (claim 17).

The examiner requires that a single disclosed species be elected for prosecution to which the claims will be restricted if no generic claim is finally held to be allowable.

Applicant hereby elects the claimed invention (1), and more specifically the entire polypeptide sequence of SEQ ID NO:24.

The examiner states that Group IV contains claims directed to the following patentably distinct species of the claimed invention:

(1) The first 663 amino acids (claim 29), and

(2) The first 241 amino acids (claim 30).

Applicant elects the entire SEQ ID NO:24 from claim 28. To the extent the examiner requires that a second species be elected, applicants elect species (1) with the first 663 amino acids (claim 29). It is understood, however, that if generic claims 13-15, 18 and 28-30 are found to be allowable, then all of the species will be examined in this case.

It is submitted that all the claims now present in the case are directed to a single invention and all should be promptly examined and found allowable in this case.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made".

Respectfully submitted,

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Version with Markings to Show Changes Made

Claim 1 has been amended as follows:

1 (Amended). An isolated polypeptide encoded by a nucleic acid molecule comprising nucleotides having a sequence set forth in SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:6, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:23 or comprising nucleotides having a sequence incorporated in a plasmid designated pCm-H-608-663-N-term, deposited under ATCC Accession No. PTA-3638, complements thereof and a polynucleotide having a sequence that differs from SEQ ID NO:1, SEQ ID NO:3, SEQ ID NO:6, SEQ ID NO:20, SEQ ID NO:22, SEQ ID NO:23 or a sequence incorporated in a plasmid designated pCm-H608-663-N-term, deposited under ATCC Accession No. PTA-3638 due to the degeneracy of the genetic code or a functional portion thereof or a polynucleotide which is at least substantially homologous or identical thereto.